

## PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 112–240, Enacted January 2, 2013]

[Currency: This publication is a compilation of the text of title XVIII of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at <https://www.govinfo.gov/app/collection/comps/>]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

[References in brackets **[ ]** are to title 42, United States Code]

### TITLE XVIII—PRESIDENT’S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

#### ESTABLISHMENT OF COMMISSION

SEC. 1801. **[300v]** (a) ESTABLISHMENT.—(1) There is established the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research<sup>1</sup> (hereinafter in this title referred to as the “Commission”) which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health, Education, and Welfare, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veterans’ Affairs, and the Director of the National Science Foundation

<sup>1</sup>Such a Commission was established on December 17, 1979, by Executive Order No. 12184 (44 Fed. Reg. 75091). The Executive Order was revoked on February 25, 1986, by Executive Order No. 12553 (51 Fed. Reg. 7237).

shall each designate an individual to provide liaison with the Commission.

(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(b) TERMS.—(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

(2) Of the members first appointed—

(A) four shall be appointed for terms of three years, and

(B) three shall be appointed for terms of two years, as designated by the President at the time of appointment.

(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

(c) CHAIRMAN.—The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

(d) MEETINGS.—(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

(e) COMPENSATION.—(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5 of the United States Code.

#### DUTIES OF THE COMMISSION

SEC. 1802. [300v-1] (a) STUDIES.—(1) The Commission shall undertake studies of the ethical and legal implications of—

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information continued<sup>2</sup> in such records,<sup>3</sup> and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this title on its own initiative or at the request of the head of the Federal agency.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) RECOMMENDATIONS TO AGENCIES.—(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

(c) REPORT ON PROTECTION OF HUMAN SUBJECTS.—The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects

<sup>2</sup>So in law. Probably should be "contained".

<sup>3</sup>So in law. The comma should probably be a semicolon.

of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) ANNUAL REPORT.—Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) made to Federal agencies by the Commission during the fiscal year and the actions taken, pursuant<sup>4</sup> to subsection (b)(2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(e) PUBLICATIONS.—The Commission may at any time publish and disseminate to the public reports respecting its activities.

(f) DEFINITIONS.—For purposes of this section:

(1) The term “Federal agency” means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

(2) The term “protection of human subjects” includes the protection of the health, safety, and privacy of individuals.

#### ADMINISTRATIVE PROVISIONS

SEC. 1803. [300v-2] (a) HEARINGS.—The Commission may for the purpose of carrying out this title hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

(b) STAFF.—(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basis pay in effect for grade GS-18 of the General Schedule.

(3) Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist it in carrying out its duties under this title.

<sup>4</sup> So in law. Probably should be “pursuant”.

(c) **CONTRACTS.**—The Commission, in performing its duties and functions under this title, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(d) **INFORMATION.**—(1) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

(2) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.

(3) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of paragraphs (4) and (6) of subsection (b) of such section.

(e) **SUPPORT SERVICES.**—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

**AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION**

**SEC. 1804. [300v-3] (a) AUTHORIZATIONS.**—To carry out this title there are authorized to be appropriated \$5,000,000 for the fiscal year ending September 30, 1979, \$5,000,000 for the fiscal year ending September 30, 1980, \$5,000,000 for the fiscal year ending September 30, 1981, and \$5,000,000 for the fiscal year ending September 30, 1982.

(b) **FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.**—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on December 31, 1982.